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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,708	07/25/2003	Atsushi Suzuki	240653US0DIV	1894

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,708	SUZUKI ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-5,8,9 and 11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,10 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/944,079.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7,9/03; 1/04,6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of Group II, claims 6-20, chlorogenic acid for species A and central nervous system stimulating components for species B in the reply filed on September 13, 2004 is acknowledged. The traversal is on the ground(s) that a search of both groups would not be burdensome because a search of Group II would overlap with a search of Group I. This is not found persuasive because while the search of both groups might overlap to some degree, they would not necessarily be coextensive. Groups I and II each require a different search strategy and each require a different analysis of the prior art. Thus, the need for two different search criteria and two different analyses demonstrates that a search burden is present.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-5, 8, 9, and 11-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 13, 2004.

4. Claims 6, 7, 10 and 20 are examined on the merits in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6, 7, 10, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite because the meaning of "central nervous stimulating component" is unclear. It is unclear what effects are considered encompassed by a "stimulation" of the central nervous system. In addition, it is unclear how to measure any potential "stimulations" to determine if such a stimulation has occurred. The specification defines this phrase as a compound that produces an "exciting effect" of the nervous system (see page 8, lines 6-7). This definition is also unclear and does not serve to better define what are "stimulating components." Page 8 of the specification provides examples of appropriate components such as ginger, red pepper and pepper, but this list is not described as a closed definition. Thus, since the specification fails to provide a complete description of "central nervous system stimulating components" and does not give means to determine when a compound is a "central nervous system stimulating component," this phrase is considered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,958,417.

US '417 teaches that Crataegus is used to treat hypertension. The reference states that the active ingredients include chlorogenic acid and caffeic acid (an organic acid with a molecular weight of 180) (see column 2, lines 55-63) and other components that can "stimulate" the nervous system. Therefore, in using Crataegus to treat hypertension, a composition of chlorogenic acid and an organic acid with the claimed molecular weight has been used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 6, 7, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (The Chinese Pharm. Journal (1994), vol. 46, pp. 575-582) and the English abstract of Japanese Patent No. 63267255.

Cheng teaches using isolated chlorogenic acid to treat hypertension (see Table 1).

JP '255 teaches using ginger to treat hypertension. Ginger is defined by applicant as a central nervous system stimulating component (see page 8).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a composition for treating hypertension. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition for treating hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

8. Claims 1, 7, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,958,417 and JP 63267255.

As discussed above, US '417 teaches a composition comprising chlorogenic acid treats hypertension.

JP '255 teaches that ginger treats hypertension.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a composition for treating hypertension. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition for treating hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 7, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,458,392. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patented claims and the pending claims are drawn to a method of treating hypertension using a composition comprising chlorogenic acid and a central nervous system stimulant. Caffeine is the central nervous system stimulant disclosed by US '392.

10. Claims 1, 7, 10, and 20 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/922,694 or Application No. 10/826,289. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to treating hypertension using a composition comprising chlorogenic acid and a central nervous system stimulant. The central nervous system stimulant in 09/922,694 and 10/826,289 is coffee.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1, 7, 10, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/632,801 and Application No. 10/810,611 in view of JP 63267255.

The claims of 10/632,801 and 10/810,611 teach using chlorogenic acid to treat hypertension.

JP '255 teaches using ginger to treat hypertension.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a composition for treating hypertension. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition for treating hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

This is a provisional obviousness-type double patenting rejection.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe

Susan D. Coe, Examiner
October 7, 2004